

EXHIBIT H

**Bescheid/Protokoll (Anlage)**

Datum
Date 02.03.2004
Date

Communication/Minutes (Annex)

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Sheet 1
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Notification/Procès-verbal (Annexe)

Anmelde-Nr.:
Application No.: 01 954 256.2
Demande n°:

The examination is being carried out on the **following application documents**:

Text for the Contracting States:

AT BE CH LI CY DE DK ES FI FR GB GR IE IT LU MC NL PT SE TR

Description, pages:

1-33 as published

Claims, No.:

1-49 as published

1.) Claims 40-43 as presently on file relate to methods for the treatment of the human or animal body by therapy. Such methods are, according to Article 52(4) EPC, not being susceptible of industrial application within the meaning of Article 52(1) EPC. Said claims relate therefore to unpatentable subject-matter and cannot be allowed (see also the Guidelines for Substantive Examination C-IV, 4.2.).

2.) Reference is made to the following document:

D1: WO 99 55320 A (SUMITOMO PHARMACEUTICALS CO., LTD.) 4
November 1999 (1999-11-04)

3.) The present application does not meet the requirements of Article 56, because the subject-matter of claims 1-7, 20-35, 37-43, 46-50 does not involve an inventive step.

D1 reports that the bitter taste of metformin can be masked by a solution comprising an organic acid and a sweetening agent, where the solution has a pH between 4-6.

Claim 1 differs from D1 in the replacement of the organic acid by a mineral acid. The problem to be solved by this difference may be regarded as to provide an

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alternative liquid composition having little unpleasant taste.

The embodiments in D1 clearly show that the bitterness (the unpleasant taste) is masked dependently on the pH. Whether this pH is adjusted by an organic acid or a mineral acid does not matter. Therefore it would be obvious for the skilled person that the organic acid can be replaced also by a mineral acid in order to mask the unpleasant taste.

The additional technical features of dependent claims 2-7, 20-31, 32-35, 37-39, 40-43, 46-50 do not contribute to any inventive step with regard to D1.

Moreover it appears that claim 1 does not solve the problem over the whole of its breadth. According to the description of the present application and to the reports in D1 the bitter taste is only reduced if the pH is greater than about 4. Thus the mere addition of the mineral acid or base does not mask bitterness.

- 4.) The use of an alkyl hydroxy ethyl cellulose and a polyhydroxy alcohol in the defined amounts for masking bitter taste of metformin in a liquid pharmaceutical composition is not disclosed or suggested in any cited document.
Therefore the subject matter of claims 8-19, 36, 44-45 appears to new and inventive.
- 5.) To meet the requirements of Rule 27(1)(b) EPC, the document D1 should be identified in the description and the relevant background art disclosed therein should be briefly discussed.
- 6.) Amended claims must meet the requirements of Article 82 EPC.